UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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DENISE MCGRATH,

Plaintiff,

- against -

BAYER HEALTHCARE PHARMACEUTICALS INC; BAYER CORPORATION; BAYER HEALTHCARE LLC; BRACCO DIAGNOSTICS, INC; and MCKESSON CORPORATION

Defendants.

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MEMORANDUM & ORDER

18 CV 2134 (RJD)(VMS)

DEARIE, District Judge:

Plaintiff Denise McGrath ("Plaintiff" or McGrath") brings failure-to-warn strict liability and negligence claims against Bayer Pharmaceuticals ("Bayer"), Bracco Diagnostics and McKesson Corporation (together, "Defendants") relating to injuries sustained as a result of exposure to Magnevist, an FDA-approved gadolinium-based contrast agent ("GBCA"), administered to patients to enhance the quality of MRIs. Plaintiff claims that prior to receiving Magnevist she was "never warned about the risks of gadolinium retention" for patients with normal renal function or advised of alternative treatment options. Second Amended Complaint ("SAC"), ECF No. 86, ¶ 10. Plaintiff alleges that she retained gadolinium in multiple organs causing "fibrosis in organs, bone, and skin" as well as "muscle pain, muscle weakness, brain fog and other injuries." Id. ¶ 5. Bayer moves to dismiss the Complaint because (i) Plaintiff's failure-to-warn claims are preempted by the FDA's regulatory scheme governing pharmaceutical labeling, and (ii) Plaintiff fails to state a plausible claim that she suffered a legally cognizable injury, or that her injury was reasonably foreseeable. For the reasons that follow, Bayer's motion to dismiss is granted.

BACKGROUND

In 2015, Plaintiff received at least one injection of Magnevist and alleges that tests performed anywhere from one to three months following the injection confirmed she retained gadolinium in her body. Id. ¶¶ 3-4, 10. Plaintiff claims she now suffers from fibrosis, muscle pain, muscle weakness, brain fog and other unspecified injuries caused by the presence of toxic levels of gadolinium in her body. Id. ¶ 5. Plaintiff further claims Defendants knew or should have known of the *risks* associated with gadolinium retention for patients with normal renal function, and failed to include an appropriate warning on the Magnevist label. Plaintiff alleges that had she been aware of such risks, she would not have exposed herself to GBCAs prior to undergoing MRIs.

Following the FDA's approval of Magnevist in 1988 Plaintiff claims that notwithstanding numerous "reports, studies, assessments, papers, peer reviewed literature, and other clinical data" describing gadolinium retention, Bayer nevertheless failed to warn "Plaintiff and her healthcare providers . . . of the *risks* posed by GBCAs." Id. ¶¶ 31-32, 34 (emphasis added). Instead, Plaintiff alleges that "claims to the public and healthcare providers" about the possibility of gadolinium retention "have been misleading and false" because they fail to "advise consumers and their healthcare providers of the causal relationship between linear [GBCAs] and gadolinium retention *resulting in fibrosis*," id. ¶¶ 34, 40 (emphasis added). Plaintiff goes on to cite a number of medical studies relating to gadolinium retention, which Plaintiff claims expose Bayer's knowledge of the *risks* associated with gadolinium retention prior to 2015. For example, Plaintiff alleges a 1989 report showed that gadolinium remained in human tissue in the days following an MRI. Id. ¶ 50. By 2004, a "major study" revealed gadolinium deposition in patients with normal renal function. Id. ¶ 45. And, in 2013, Japanese researchers found

evidence of gadolinium retention in the brains of patients with normal renal function, which was "confirmed by scientists at the Mayo Clinic in 2014." Id. ¶¶ 70-71. Plaintiff alleges the Mayo Clinic study prompted the FDA to issue a "public safety alert" stating it was evaluating the risk of brain deposits from repeated exposure to GBCAs. Id. ¶¶ 71-72.

In 2017, two years after Plaintiff's treatments, "the FDA's medical advisory committee voted 13 to 1 in favor of adding a warning on [GBCA] labels that *gadolinium can be retained* in some organs, including the brain, even in patients with healthy kidneys." Id. ¶¶ 73-74; Defs.' Br., Ex. B, ECF No. 79-5. The amendment reflects new information supporting the *fact* of gadolinium retention in patients with normal renal function but does not reference any *risks* associated with gadolinium retention. Plaintiff claims Defendants' failure to warn her and her healthcare providers of the *risks* associated with gadolinium retention in patients with normal renal function was "a substantial factor" in bringing about her injuries.

After the parties briefed Bayer's motion to dismiss, the Court heard oral argument and pointed out that the absence in the Complaint of "newly-discovered scientific evidence" or "literature that makes the causal connection" between gadolinium retention and fibrosis undercut Plaintiff's failure-to-warn claims and made a strong case for preemption. May 3, 2019 Oral Argument, ECF No. 87-1, at 10:25, 15:6-7. Plaintiff represented at oral argument that literature making the requisite causal connection was available, and on May 27, 2019, filed a Second Amended Complaint. However, the added allegations do not plausibly allege the causal connection required to justify a unilateral label change under the CBE regulation, and, in any event, the information was not available in 2015 when Plaintiff was administered Magnevist. Plaintiff thus fails to state a failure-to-warn claim that is not preempted: her allegations regarding the causal association between Magnevist injections, gadolinium retention *and* a

significant adverse reaction—such as fibrosis—are conclusory and grounded in hypothesis rather than scientific evidence capable of raising at least a reasonable expectation that Plaintiff is entitled to the relief she seeks.

LEGAL STANDARD

In deciding a motion to dismiss, the court must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." LaFaro v. N.Y. Cardiothoracic Grp., PLLC, 570 F.3d 471, 472 (2d Cir. 2009). Ultimately, the Complaint must allege sufficient facts which, taken as true, state a plausible claim for relief. Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 656 (S.D.N.Y. 2017) (citing Keiler v. Harlequin Enterprises ltd., 751 F.3d 64, 68 (2d Cir. 2014)). A claim is plausible when the pleaded factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). To do so, the Plaintiff must plead more than the mere possibility that she is entitled to relief, but need not go so far as to demonstrate that relief is probable. This "plausibility standard" requires the plaintiff state "more than labels and conclusions" or "a formulaic recitation of the elements of a cause of action." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007), and instead plead facts sufficient to "raise a reasonable expectation that discovery will reveal evidence supporting [her] claim for relief," Pension Benefit Guar. Corp. ex rel. St. Vincent Catholic Med. Ctrs. Retirement Plan v. Morgan Stanley Inv. Mgmt. Inc., 712 F.3d 705, 729 (2d Cir. 2013). "[W]hen considering a preemption argument in the context of a motion to dismiss, the factual allegations relevant to preemption must be viewed in the light most favorable to the plaintiff. A district court may find a claim preempted only if the facts alleged in the complaint do not plausibly give rise to a claim that is not

preempted." Utts, 251 F. Supp. 3d at 672 (quoting Galper v. JP Morgan Chase Bank, N.A., 802 F.3d 437, 444 (2d Cir. 2015)).

DISCUSSION

I. Motion to Dismiss Plaintiff's Failure-to-Warn Claims as Preempted

a. Legal Standard

Though Plaintiff claims that as of 2015 the Magnevist label should have warned against the risk of injury from gadolinium retention, Bayer argues it would have been impossible to implement such a warning using the "Changes Being Effected" ("CBE") regulation, and thus Plaintiff's failure-to-warn claims are preempted by the CBE regulation and the FDA's warning labeling scheme. The CBE regulation set forth in 21 C.F.R. § 314.70(c)(6)(iii) allows drug manufacturers to change a drug label unilaterally, and without FDA preapproval, "if the changes add or strengthen a contraindication, warning, precaution, or adverse reaction" or "add or strengthen an instruction about dosing and administration that is intended to increase the safe usage of the drug product in order to reflect newly acquired information." Id. If a plaintiff shows that "defendants could unilaterally change the label . . . without FDA approval," the burden shifts to the manufacturer to show "by clear evidence that the FDA would not have approved the labeling change." Utts, 251 F. Supp. 3d at 661. On the other hand, a drug manufacturer can show that a plaintiff's failure-to-warn claims are preempted by the FDA's regulatory scheme for drug warnings "(1) by showing that it was prohibited by federal law from [unilaterally] modifying the FDA-approved labeling; *or* (2) by presenting clear evidence that the FDA would not have approved a change to the drug's label." Byrd v. Janssen Pharm, Inc., 333 F. Supp. 3d 111, 120 (N.D.N.Y. 2018) (emphasis added) (citing Amos v. Biogen Idec Inc., 249 F. Supp. 3d 690, 699 (W.D.N.Y. 2017)).

"Newly acquired information" under the CBE regulation includes "data, analyses, or other information not previously submitted to the FDA, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to the FDA." Utts, 251 F. Supp. 3d at 659 (citing 21 C.F.R. § 314.70(c)(6)(iii)); see also id. at 661 ("Because manufacturers may unilaterally update a drug's label if the change complies with the CBE regulation, a state law failure-to-warn claim that depends on newly acquired information . . . is not preempted."). Moreover, newly acquired information "must provide *reasonable evidence* of a causal association of a clinically significant adverse reaction linked to a drug." 21 C.F.R. §201.57(c)(6)(i) (emphasis added). A clinically significant adverse reaction "ha[s] a significant impact on therapeutic decision-making, such as a risk that is *potentially fatal or otherwise serious*." Id. (emphasis added). The FDA imposes this standard because it "recognize[s] that exaggeration of risk, or *inclusion of speculative or hypothetical risks*, could discourage appropriate use of a beneficial drug . . . or decrease the usefulness and accessibility of important information by diluting or obscuring it. Indeed, labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful risk information to lose its significance." Utts, 251 F. Supp. 3d at 659 (emphasis added) (citing 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008)); see also Merck Sharp & Dohme Corp. v. Albrecht, 139 S.Ct. 1668, 1673 (2019). As a result, "the CBE regulation requires that there be sufficient evidence of a causal association between the drug and the information sought to be added"—here, between Magnevist injections and a warning regarding the *risks* of gadolinium retention, such as fibrosis. Utts, 251 F. Supp. 3d at 659.

b. Application

Bayer claims Plaintiff's failure-to warn-claims are preempted principally because the Complaint is devoid of any plausible allegations of "newly acquired information" establishing a "causal association" between injections of Magnevist and a "clinically significant adverse reaction" in patients with normal kidney function. Specifically, Bayer argues the allegations in the Complaint that cite to studies relating to "mere retention of trace amounts of gadolinium in patients' bodies after using GBCAs" do not plausibly allege any *risks* associated with gadolinium retention or otherwise constitute a "clinically significant adverse reaction" warranting a label change under the CBE regulation. On the other hand, Plaintiff relies on the Supreme Court's recent decision in Merck Sharp & Dohme Corp. v. Albrecht, 139 S.Ct. 1668 (2019) to argue there is no "clear evidence" the FDA would have rejected a warning articulating "the risks" associated with gadolinium retention. Plaintiff also contends that "the relief [she] seeks is dependent upon a fact-intensive record that can only be developed through discovery" and Bayer's arguments do not otherwise fit within the "narrow exception to the rule against preemption" in failure-to-warn product liability cases. Pl. Br., ECF No. 82, at 7-8.

Though "manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times," drug manufacturers are nevertheless "limited in their ability to unilaterally change the labels on their products" because they must comply with the FDA's CBE regulation. Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 707 (2d Cir. 2019) (quoting Wyeth v. Levine, 555 U.S. 555, 579 (2009)). Plaintiff's allegations do not state a plausible claim that, in 2015, Bayer knew or should have known of "new information" indicating a "causal association" between exposure to Magnevist and a "clinically significant adverse reaction"—here, fibrosis—in patients with normal renal function. Plaintiff's allegations focus on gadolinium retention,

which is not, by itself, the "clinically significant adverse reaction" Plaintiff complains of. To date, the incidence of any *risks* associated with gadolinium retention is inconclusive and is, at best, only marginally supported by data gathered *after* Plaintiff's Magnevist injections. For the Court to draw the reasonable inference that Bayer could have unilaterally amended the Magnevist label in compliance with the FDA's CBE regulation, the Complaint must plead more than the mere possibility that Magnevist caused Plaintiff's fibrosis and related injuries. And, the more recent scientific studies in Plaintiff's Second Amended Complaint, do not compel a contrary conclusion: not only were these studies published after Plaintiff received injections of Magnevist, but in any event, they do not plausibly allege the requisite causal connection under the FDA's regulatory scheme.

First, assuming Plaintiff points to "newly acquired information" since the FDA's approval of Magnevist in 1988, none of that information shows an "adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling." 21 C.F.R. § 314.70(c)(6)(iii)(A); see also Albrecht, 139 S.Ct. at 1673. Instead, the evidence only builds upon the fact that following exposure to Magnevist, gadolinium can be retained in patients with normal renal function, but it does not identify any *risks* associated with gadolinium retention. For example, Plaintiff describes a 2004 study in which "gadolinium was shown to be deposited in the resected femoral heads (bones) of people who had undergone gadolinium MRI studies" and subsequent studies that "continue[] to indicate that gadolinium remains within people's bodies long after the suggested half-life." SAC ¶ 52. Similarly, Plaintiff described a 2013 study finding "evidence of retained gadolinium in the brains of patients with normal renal function," including "hyperintense signals in critical areas of the brain." Id. ¶ 70.

Reports and studies that discuss the *fact* of gadolinium retention but do not reach any conclusions regarding the *adverse effects* or *risks* associated with gadolinium retention in patients with normal renal function "do not plausibly allege the existence of newly acquired information that could have justified Defendants' revising the [Magnevist] label through the CBE regulation." Gibbons, 919 F.3d at 708. To the contrary, though "historical literature indicates gadolinium retention in healthy patients is occurring...*the clinical consequences of deposition remain unknown.*" JE Huckle et al., Gadolinium Deposition in Humans: When did We Learn That Gadolinium was Deposited in Vivo?, Invest Radiology (2016) (emphasis added); SAC ¶ 44 & n.11. While the Complaint includes more than "conclusory and vague" references to "reports" and "studies" that compelled the Second Circuit to conclude preemption was warranted in Gibbons, it helps precious little to mount scientific minutiae on top of technical jargon if that information ultimately does not plead a plausible causal association between Magnevist and adverse effects, like fibrosis. Compare with Gibbons, 919 F.3d at 708 ("reports of serious hemorrhaging" and "numerous studies" that "confirm the problematic bleeding events" revealed no new or more significant risks and thus unilateral label change was warranted). Because Plaintiff's failure-to-warn claims depend upon Bayer's failure to warn of the *risks* of gadolinium retention, plausible allegations that relate only to the *fact* of gadolinium retention do not suffice.

Second, of the new studies cited in the Second Amended Complaint most are inconclusive regarding the risks, if any, associated with gadolinium retention and would not justify a unilateral label change. One explains that "to date, it remains unknown whether [GBCAs] induce toxic effects on the cellular function of human neurons," SAC ¶ 6 & n.1, and another similarly concludes that "further studies are required to address possible clinical consequences of gadolinium deposition in the skin, brain and potentially other organs in patients

with normal renal function," SAC ¶ 9 & n.9. One study, electronically published *after* oral argument and not yet replicated, purports to uncover "the first evidence" that GBCA exposure causes "significant metabolic disorders and kidney injury in *mice* without renal insufficiency." Catherine Do et al., Gadolinium-based Contrast Agents: Stimulators of Myeloid-Induced Renal Fibrosis and Major Metabolic Disruptors, Elsevier Toxicology and Applied Pharmacology (July 2019) (emphasis added); SAC ¶ 7, & n.2.

"The FDA has recognized that "exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug...or decrease the usefulness and accessibility of important information by diluting or obscuring it." Albrecht, 139 S.Ct at 1673; Utts, 251 F. Supp. 3d at 661 (citing Supplemental Application Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008)); 21 C.F.R. § 201.57(c)(6)(i). Thus, to ensure that only "scientifically accurate information appears in the approved labeling" the FDA prefers a more cautious approach, and finds that because "labeling that includes theoretical hazards not *well-grounded* in scientific evidence can cause meaningful risk information to lose its significance," there must be "*sufficient* evidence of a causal association between the drug and the information sought to be added." Utts, 251 F. Supp. 3d at 659. Studies concluding it "remains unknown whether GBCAs induce toxic effects" and that "further studies are required to address possible clinical consequences of gadolinium deposition...in patients with normal renal function" do not constitute reasonable or well-grounded scientific evidence of "clinically significant adverse effects" under the CBE regulation. To find otherwise would permit the "inclusion of speculative or hypothetical risks" absent "sufficient evidence of a causal association between [Magnevist] and [the risks associated with gadolinium retention]," and based instead on the bare and

conclusory allegation that Plaintiff suffers from fibrosis as a result of gadolinium retention. Id. at 659; Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011) ("The fact that a user of a drug has suffered an adverse event, standing alone, does not mean that the drug caused that event").

Even the cited month-old study finding a connection between exposure to GBCAs and "significant metabolic disorders and kidney injury in mice," does not provide "well-grounded" or "sufficient evidence of a causal association between the drug and the information sought to be added." Utts, 251 F. Supp. 3d at 659. The study has yet to be replicated, and only demonstrates an adverse reaction in mice. This dearth of evidence cannot be reconciled with the Supreme Court's recent decision in Albrecht, which explained that only "when the risks of a particular drug become *apparent*, the manufacturer has a duty to provide a warning that adequately describes the risk." 139 S.Ct. at 1677. Indeed, the FDA contemplated that the CBE regulation would be used sparingly, noting it "would not allow a change to labeling to add a warning in the absence of *reasonable evidence* of an association between the product and an adverse event." Supplemental Application Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (Jan. 16, 2008) (allowing a unilateral change based only on "known hazards and not theoretical possibility," "sufficient evidence of a causal association," or "reasonable evidence of an association"); see also Wyeth, 555 U.S. at 571 ("requiring a manufacturer to revise its label to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"). A single study performed on mice does not make a risk "apparent" or otherwise constitute "reasonable evidence of an association" between Magnevist and fibrosis. And, even if this study could adequately plead a causal association between Magnevist and "clinically significant adverse effects," it was published after

Plaintiff's exposure to Magnevist and thus cannot support a failure-to-warn claim based on what Bayer knew or should have known in 2015.

Finally, Plaintiff's eleventh-hour attempt to rely on the Supreme Court's decision in Albrecht to avoid preemption and resurrect her claims is misplaced. In Albrecht, the drug manufacturer "conceded that the FDA's CBE regulation would have permitted [it] to try to change the label to add a warning before [the FDA required it to do so in] 2010." 139 S.Ct. at 1675. Here, on the other hand, Bayer argues, and the Court agrees, that Plaintiff has not pleaded a plausible claim that the CBE regulation would have permitted Bayer to change the Magnevist label to reflect *risks* associated with gadolinium retention. Indeed, in Albrecht, before the FDA required the drug manufacturer to update its warning, the manufacturer "performed a statistical analysis of [the drug's] adverse event reports, concluding that these reports revealed a statistically significant incidence of femur fractures" and "about the same time, [the manufacturer] began to see numerous scholarly articles and case studies documenting possible connections between long-term [drug] use and atypical femoral fractures." Id. at 1674. In Albrecht, this medical evidence revealed a reasonable, if not compelling, causal association—the kind of causal association the FDA contemplated before a drug company could unilaterally amend a warning under the CBE regulation. For the reasons set forth above, such a causal connection is absent here and because Bayer could not have amended the warning under the CBE regulation, this Court need not even consider whether there is clear evidence the FDA would not have approved a change to Magnevist's label. Ultimately, the allegations in the Complaint that Plaintiff's "adverse reaction" resulted from exposure to Magnevist are based on Plaintiff's own conclusory allegations, unsupported by medical evidence available at the time of Plaintiff's Magnevist injections. Accordingly, the Complaint fails to state a plausible claim that

Bayer could have unilaterally changed its label under the CBE regulation, and Plaintiff's failure-to-warn claim is preempted.

II. Motion to Dismiss for Failure to State a Claim

Alternatively, Bayer claims that Plaintiff fails to state a failure-to-warn claim under negligence or strict liability theories because (i) retention of gadolinium is not alone a legally cognizable injury under New York tort law, (ii) the complained of "fibrosis and related injuries" were not reasonably foreseeable, (iii) "related injuries" are too vague to satisfy Rule 8 pleading requirements and (iv) Plaintiff's strict liability and negligence claims are too vague and sprawling to pass muster under Fed. R. Civ. P. 8. Plaintiff responds that she has adequately alleged (i) gadolinium retention as a "primary injury" which "causes fibrosis in organs, bone, and skin . . . and deposits in the neuronal nuclei of the brain" and (ii) that gadolinium retention was reasonably foreseeable in light of the "numerous case reports, studies, assessments, papers, peer reviewed literature, and other clinical data."

"Under New York law failure to warn claims are identical under strict liability and negligence theories." DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2011). Accordingly, "a pharmaceutical manufacturer has a duty to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." Id. A manufacturer will thus incur liability where (i) the manufacturer had a duty to warn, (ii) the manufacturer breached the duty to warn in a manner that rendered the product defective, i.e., reasonably certain to be dangerous, (iii) the defect was the proximate cause of the plaintiff's injury and (iv) the plaintiff suffered loss or damage. Bee v. Novartis Pharmaceutical Corp., 18 F. Supp. 3d 268, 282 (E.D.N.Y. 2014) (citing McCarthy v. Olin Corp., 119 F.3d 148, 156 (2d Cir. 1997)). Moreover, "a manufacturer has a duty to warn against latent dangers resulting from

foreseeable uses of its product of which it knew or should have known." Id. "This duty is a continuous one, and requires that the manufacturer be aware of the current information concerning the safety of its product." Id.

Though Plaintiff pleads a legally cognizable and specifically articulated injury that adequately put Defendants on notice of her claim, she does not plausibly plead causation—that her injuries were caused by Bayer's failure to warn her of the risks associated with gadolinium retention—or that such injuries were reasonably foreseeable to Bayer. Bayer contends "a threat of future harm is insufficient to impose liability against a defendant in a tort context," but Bayer mischaracterizes the nature of the physical harm Plaintiff alleges in her Complaint. Plaintiff's failure-to-warn claim is premised on Bayer's failure to warn of the *risks* associated with gadolinium retention, like fibrosis, but she repeatedly claims that the gadolinium retained in her body *actually resulted* in fibrosis, not merely risk of fibrosis. Bayer relies on Caronia v. Philip Morris USA, Inc., 5 N.E. 3d 11, 14 (N.Y. 2013), where Plaintiffs failed to plead a legally cognizable injury by alleging exposure to carcinogens in cigarettes put them at *risk* of developing lung cancer. However here, Plaintiff alleges an actual physical injury—fibrosis—occurred as a result of Defendants' failure to warn her of the *risks* associated with gadolinium retention.

Plaintiff nevertheless fails to state a failure-to-warn claim because she has not adequately pleaded that her injuries were caused by Bayer's failure to warn or were otherwise reasonably foreseeable to Bayer. In the same way Plaintiff fails to plead a "causal association" between any new information regarding gadolinium retention and an "adverse effect", e.g., fibrosis, she similarly fails to plead that such an adverse effect was "reasonably foreseeable" based on what Bayer knew or should have known in 2015. Burkett v. Smith, 2014 WL 1315315, at *6 (E.D.N.Y. Mar. 31, 2014) (dismissing plaintiff's failure-to-warn claim as preempted because she

"fail[ed] to link the purported violation to her injury"). Absent a causal link between gadolinium retention and a cognizable injury like fibrosis, Plaintiff's injury was not "reasonably foreseeable" and thus Bayer's duty to warn was never triggered.

CONCLUSION

Plaintiff's failure-to-warn claims are preempted because she does not plead a plausible causal association between Magnevist and fibrosis that Bayer knew or should have known about in 2015. Alternatively, Plaintiff fails to state a plausible claim that injury was reasonably foreseeable to Bayer as a result of her exposure to Magnevist. Plaintiff's claims are dismissed.

SO ORDERED.

Dated: Brooklyn, New York
June 24, 2019

s/ Raymond J. Dearie

RAYMOND J. DEARIE
United States District Judge